REMARKS

Reconsideration in view of the above amendments and the following remarks is respectfully requested. Claims 1-231 were pending. Claims 3-12, 16-19, 55-64, 73-89, 94-97, 100, 101, 103-113, 116, 117, 148-157, 165-181, 193-197, and 204-231 have been canceled without acquiescing to the rejections in the Office Action or prejudice to future prosecution in a related application. New claims 232-237 have been added. Accordingly, claims 1, 2, 13-15, 20-54, 65-72, 90-93, 98, 99, 102, 114, 115, 118-147, 158-164, 182-192, 198-203, and 232-237 are pending. Support for new claims 232, 236 and 237 may be found, for example, at page 10, lines 10 and 11 of the present application. Support for new claim 233 may be found, for example, at page 24, lines 15-17. Support for new claims 234 and 235 may be found, for example, at page 52, lines 6-8. No new matters have been added via the addition of these new claims.

Claims 1, 2, 13-15, 20-26, 35, 37, 41, 44, 48, 53, 54, 67, 72, 98, 102, 114, 115, 118-125, 131, 132, 139, 142, 146, 147, 159, 164, 189, 191, and 198 have been amended. Such amendments have been made without acquiescing to the rejections in the Office Action or prejudice to future prosecution of previously pending claims in a related application. Support for the amendments to claims 1 and 198 may be found, for example, in original claims 9, 16 and 17, at page 14, lines 15-24, and at page 42, lines 13-17. The amendments to the other claims are to change dependency or enter minor changes. No new matter has been added via the amendments to the claims.

The specification has been amended to correct errors resulting from global replacements of "can" with "may" and to correct other typographical errors. No mew matter has been added via the amendments to the specification.

Election/Restriction

In the Office Action, Applicants' election with traverse of Group I, claims 1-93, in the reply filed October 26, 2006, is acknowledged. However, it is stated in the Office Action that "[t]he traversal is on the ground(s) that requiring election of species based on the BAB or ABA or alginate or chitosan or polyurethane or hyaluronic acid or

is improper because claim 17 is generic to the species found in claims 20-54. This is not found persuasive because claim 20 is a film, claim 21 is a wrap, claim 22 is a gel, claim 23 is a foam, claim 24 is a mold and claim 25 is a coating. The search for these different species in separate claims is a burden on the search and consideration process."

Applicants respectfully disagree with the above discussion of Applicants' traversal to the Restriction Requirement in the Office Action. Applicants' traversal in the response to the Restriction Requirement is directed to the species election in A) C(i) and A C(ii) of paragraph 11 at page 5 of the Restriction Requirement dated September 27, 2006. A) C(i) and A) C(ii) are reproduced below for easy reference:

> C(i) Furthermore, if applicant elects polymeric carrier, then applicant must further elect a specific ABA biodegradable polymer carrier or BAB biodegradable polymer carrier; and C(ii) if applicant elects non-polymeric carrier, applicant must further elect hyaluronic acid or chitosan or alginate or poly(urethane) or poly(hydroxyethylmethacrylate)

In the response to the Restriction Requirement, concerning A) C(i), Applicants note that claims 34-41, 42-45, and 46-49 are directed to three types of block copolymers: (1) a diblock copolymer having a first block and a second block (*see*, claims 34-41); (2) a triblock copolymer comprising a structure of A-B-A (*see*, claims 42-45); and (3) a triblock copolymer comprising a structure of B-A-B (*see*, claim 46-49). Thus, the species election in A) C(i) should not be limited to a triblock polymer (*e.g.*, a specific ABA biodegradable polymer carrier or BAB biodegradable polymer carrier), but should include a diblock polymer, as well as the polymer carriers listed in A) C(ii) as discussed below.

Concerning A) C(ii), Applicants note that hyaluronic acid, chitosan, alginate, poly(urethane), and poly(hydroxyethylmethacrylate) are all polymer carrier, not non-polymeric carriers. Accordingly, they should be included in A) C(i), not in A) C(ii). In contrast, the carriers recited in claims 57 and 59-64 are non-polymeric carriers and should be included in A) C(ii).

Applicants further respectfully disagree with the disposal of claim 21 and request that this claim be examined in the present application with claims 1-4, 8-14, 16, 17, 26, 27, 34-41, 67-69, and 72. More specifically, Applicants elected wrap (*see*, claim 21) in response to the

species election according to A) b) of paragraph 11 on page 5 of the Restriction Requirement. Thus, claim 21 reads on the elected wrap and should be examined in the present application.

Applicants further submit that new claims 232, 234 and 235 all read on the elected invention and species, and thus should be considered in the present application. New claims 233, 236 and 237 are directed to the non-elected invention or species, and should be withdrawn from consideration in the present application, but may be rejoined if the claims directed to the elected invention and species become allowable.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-4, 8, 9 14, 16, 17, 26, 27, 34-37, 67-69 and 72 are rejected under 35 U.S.C. 102(b) as anticipated by Hunter *et al.* (U.S. Patent No. 5,716,981, referred to below as "Hunter").

To facilitate allowance and without acquiescing to the rejection in the Office Action, Applicants have amended claim 1 to recite a delivery device that comprises (i) an antiproliferative agent, (ii) a polymer carrier of the antiproliferative agent, and (iii) a mesh, wherein the mesh comprises poly(lactide-co-glycolide) with a lactide:glycolide ratio ranging from 3:97 to 15:85. Applicants submit that the delivery device now recited in amended claim 1 has not been disclosed in Hunter. More specifically, Hunter does not disclose a mesh that comprises poly(lactide-co-glycolide) with a lactide:glycolide ratio ranging from 3:97 to 15:85. Accordingly, Hunter does not anticipate claim 1 and its dependent claims. In addition, Hunter does not disclose a methoxypoly(ethylene glycol):polyester ratio in the range of about 10:90 to about 30:70 as recited in claim 38, or a methoxypoly(ethylene glycol):polyester ratio of about 20:80 as recited in claim 39. Accordingly, Hunter does not anticipate claims 38 and 39.

Claims 1, 3, 4, 8, 9, 14, 16, 17, 26, 34-37 and 72 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yang *et al.* (Current Opinion in Colloid & Interface Science 5(1): 132-43, 2000, referred to below as "Yang").

As indicated above, amended claim 1 now recites a delivery device that comprises (i) an antiproliferative agent, (ii) a polymer carrier of the antiproliferative agent, and (iii) a mesh, wherein the mesh comprises poly(lactide-co-glycolide) with a lactide:glycolide ratio ranging

from 3:97 to 15:85. Applicants submit that the claimed delivery device has not been disclosed in Yang. First, Yang fails to disclose a delivery device that comprises a mesh as this term recited in claim 1 of the present application would be understood by one of ordinary skill in the art in view of the present application. Yang relates to delivery and release of drugs (especially protein drugs) from polymer-based **colloids**. The only location where "mesh" is mentioned in this reference relates to polymerization of polymerizable lipids having functional groups linked to the polar head of the lipids. After polymerization of these functional groups attached on the liposome surface, a polymer **mesh**-like network forms with the liposome sheltered inside. The "**mesh**" in Yang is different from the **mesh** recited in the claims of the present application. The present application provides that a mesh, as used in the present application, is a material composed of a plurality of fibers or filaments (*i.e.*, fibrous material), where the fibers or filaments are arranged in such a manner as to form a porous structure (*see*, page 35, lines 23-26 of the present application). It further provides that typically a mesh is a pliable material, such that it has sufficient flexibility to be wrapped around the external surface of a body passageway or cavity, or a portion thereof (*see*, page 35, lines 27 and 28 of the present application). The present application also provides that the mesh is capable of providing support to the structure (*e.g.*, the vessel or cavity wall) and may be adapted to release an amount of a therapeutic agent (*see*, page 35, line 28 to page 36, line 2 of the present application). One of ordinary skill in the art, in view of the present application, would not regard the polymer **mesh**-like network formed outside liposome as the **mesh** recited in the claims of the present application. In addition, the mesh-like network in Yang is made of polymerizable **lipids**, not **poly(lactide-co-glycolide)** as recited in amended claim 1. Furthermore, Yang fails to disclose the specific lactide:glycolide ratio range recited in amended claim 1. Moreover, Yang fails to mention any diblock copolymer having **methoxypolyethylene glycol** as the first block and a polyester as the second block recited in claim 34 and its dependent claims 35-41, or the methoxypoly(ethylene glycol):polyester ratio range recited in claim 38 (*i.e.*, about 10:90 to about 30:70), the specific methoxypoly(ethylene glycol):polyester ratio recited in claim 39 (*i.e.*, about 20:80), the molecular weight range of methoxypoly(ethylene glycol) recited in claim 40 (*i.e.*, about 200 g/mol to about 5000 g/mol), or the specific molecular weight of methoxypoly(ethylene glycol) recited in claim 41 (*i.e.*, about

750 g/mol). Accordingly, Yang does not anticipate claim 1 and its dependent claims, especially claims 34-41.

In view of the above remarks, Applicants submit that this ground of rejection under 35 U.S.C. 102(b) has been overcome. Withdrawal of these rejections is respectfully requested.

Claim Rejection Under 35 U.S.C. § 103

Claims 10-13 and 38-41 stand rejected under 35 U.S.C. 103(a) as unpatentable over Hunter in view of Chern *et al.* (U.S. Patent No. 6,733,767, referred to below as "Chern").

Applicants respectfully traverse this ground of rejection. As discussed above, Hunter does not disclose (1) a mesh that comprises poly(lactide-co-glycolide) with a lactide:glycolide ratio ranging from 3:97 to 15:85 recited in amended claim 1, (2) the methoxypoly(ethylene glycol):polyester ratio range recited in claim 38 (*i.e.*, about 10:90 to about 30:70), or (3) the methoxypoly(ethylene glycol):polyester ratio recited in claim 39 (*i.e.*, about 20:80). Such deficiencies have not been remedied by Chern. Chern relates to **liquid** polymeric compositions for controlled release of bioactive substances. PLGA is a component of the **liquid** compositions (which also comprise at least one bioactive substance, and a mixture of at least one hydrophilic solvent and at least one lipophilic solvent), not a material that forms a mesh as recited in claim 1 of the present application. In addition, the **lactide:glycolide ratio** of PLGA disclosed in Chern is from 95:05 to 50:50. In other words, lactide is present in the same amount as, or in an amount more than, glycolide in PLGA according to Chern. To the contrary, the lactide:glycolide ratio of PLGA recited in claim 1 of the present application ranges from 3:97 to 15:85. Thus, the PLGA recited in claim 1 contains significantly less lactide than glycolide. Accordingly, the combination of Hunter and Chern would not arrive at the subject matter claimed in the present application. In addition, Chern is silent on a diblock copolymer with **methoxypolyethylene glycol** as the first block and a polyester as the second block, and does not teach or suggest any particular ratio or range of methoxypoly(ethylene glycol):polyester in the diblock copolymer. Thus, the combination of Hunter and Chern would not arrive at the subject matter recited in claim 38 or claim 39.

Applicants further submit that one of ordinary skill in the art would not have combined Hunter with Chern. PLGA is disclosed in Hunter as a polymeric carrier of an anti-angiogenic agent. According to Hunter, a composition that comprises an anti-angiogenic agent and a polymeric carrier of the anti-antiogenic agent may be used to coat a surgical mesh or coat or form a mesh into which a stent may be inserted (*see*, column 26, lines 20-29 and column 22, lines 50-52 of Hunter). Thus, in Hunter, PLGA is either as a component of a coating on a surgical mesh or a component of a coating or otherwise a part of a mesh into which a stent may be inserted. To the contrary, PLGA is a component of a **liquid** composition that stays as a film-coated (encapsulated) liquid rather than forming a solid, gel or coagulated mass (including "pore-containing" solids, gels, or masses) (*see*, column 3, line 66 to column 4, line 6 of Chern). In addition to PLGA, the liquid composition of Chern also requires the presence of a mixture of at least one hydrophilic solvent and at least one lipophilic solvent (*see*, column 4, lines 42-43 of Chern). Because the compositions in which PLGA is present in Hunter are significantly different from those in Chern, one of ordinary skill in the art would not have combined these two references.

Claims 10-13 and 38-41 stand rejected under 35 U.S.C. 103(a) as unpatentable over Yang in view of Chern. As discussed above, Yang fails to teach or suggest (1) a delivery device that comprises a mesh as this term recited in claim 1 of the present application would be understood by one of ordinary skill in the art in view of the present application, (2) a mesh that comprises poly(lactide-co-glycolide) with a lactide:glycolide ratio recited in amended claim 1 (*i.e.*, 3:97 to 15:85), (3) the methoxypoly(ethylene glycol):polyester ratio range recited in claim 38 (*i.e.*, about 10:90 to about 30:70), or (4) the methoxypoly(ethylene glycol):polyester ratio recited in claim 39 (*i.e.*, about 20:80). The above deficiencies have not been remedied by Chern. As discussed above, PLGA is a component of **liquid** compositions in Chern, not a material that forms a mesh as recited in claim 1 of the present application. In addition, the lactide:glycolide ratio of PLGA disclosed in Chern (*i.e.*, from 95:05 to 50:50) is significantly different from that recited in claim 1 of the present application (*i.e.*, from 3:97 to 15:85). In addition, Chern is silent on a diblock copolymer with methoxypolyethylene glycol as the first block and a polyester as the second block, and does not teach or suggest any particular ratio or range of

methoxypoly(ethylene glycol):polyester in the diblock copolymer. Accordingly, the combination of Yang and Chern would not arrive at the subject matter claimed in the present application.

Applicants further submit that one of ordinary skill in the art would not have combined Yang with Chern. First, Yang focuses on delivery and release of proteins (most of them **hydrophilic**) from polymer-based colloids, whereas Chern relates to controlled release of **hydrophobic** bioactive substances. Second, PLGA is disclosed in Yang as a polymeric matrix to reduce protein denaturation in **nano- and microparticles** or as a **hydrogel** to which drugs may be loaded. To the contrary, PLGA in Chern is a component of a **liquid** composition that stays as a film-coated (encapsulated) liquid rather than forming a **solid**, **gel** or coagulated mass (including "pore-containing" solids, gels, or masses) (*see*, column 3, line 66 to column 4, line 6 of Chern). In addition to PLGA, the liquid composition of Chern also requires the presence of a mixture of at least one hydrophilic solvent and at least one lipophilic solvent (*see*, column 4, lines 42-43 of Chern). Because the compositions in which PLGA is present in Yang are significantly different from those in Chern, one of ordinary skill in the art would not have combined these two references.

In view of the above remarks, Applicants submit that this ground of rejection under 35 U.S.C. 103(a) has been overcome. Withdrawal of these rejections is respectfully requested.

Claim Objections

Claim 13 stands objected to under 37 C.F.R. 1.75(c) as in improper form.

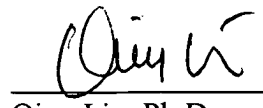
Applicants thank the Examiner for noting this informality and have amended claim 13 to eliminate improper multiple dependency. Accordingly, withdrawal of this objection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants believe that all of the claims remaining in the application are now allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Qing Lin, Ph.D.
Registration No. 53,937

QXL:kw

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

1094696_1.DOC